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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,028	03/11/2004	Ernest Aranyi	2891	6009

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/798,028	ARANYI ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/10/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7/10/2006 have been fully considered but they are not persuasive.

In response to applicant's argument that the device disclosed by Sherman is not a clip applying apparatus as claimed in claim 19 but instead a clamp applying apparatus, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The soft material on the insides of each jaw would not prohibit the jaws from closing a clip that is disposed between them.

In response to applicant's arguments that Castro et al. teaches away from using the device to apply clips due to the recitation of teeth along the jaws, the examiner respectfully disagrees. This is the intended use of the device and Castro et al. meets the structural limitations of the claims 1, 2, and 7 except for the radius of curvatures. If a user were to insert a clip between jaws (36) and (38) and close the jaws, a clip can be applied. The fact that the jaws can be rotated ("E") means that at some point the jaws will be curved upwardly regardless of the orientation of the device.

In response to applicant's arguments concerning the 35 U.S.C. 103 rejections of claims 1-11 over Pistl et al. (U.S. 5,626,586) in view of Klieman et al. (U.S. 4,325,376), applicant argues that the Pistl et al. does not disclose a curved jaw structure. However, as seen in Fig. 2, even if the jaws are straight planar members that are merely tilted as the applicant states, the jaw is curved at the spot where the jaw goes from being parallel to the longitudinal axis of the body portion of the device to a tilted configuration. Furthermore, Klieman et al. teaches the use

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of curved jaws as seen in fig. 4 and further states that the jaws are curved (col. 6 ll. 57-63).

Klieman et al. discloses that curved jaws are advantageous because they improve visibility.

Applicant also argues that the jaws of Klieman et al. are oriented downwardly instead of upwardly. However, the use of upwardly depends on the orientation of the device. This will depend on how the surgeon is holding the device, which may change during an operation or from surgeon to surgeon.

In response to applicant's argument that neither Castro et al., Pistl et al., nor Klieman et al. discloses or suggests a curved jaw with a radius of curvature between about .5 inches and about .9 inches, Applicant has not disclosed that this particular radius of curvature provides any advantage, is used for a particular purpose, or solves a stated problem. In the case of Castro et al., the use of a Fogarty clamp does not teach away from this radius of curvature since Fogarty clamps have a range of shapes and curves. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Castro et al. or the device of Pistl et al. (as modified in view of Klieman et al.) to include a radius of curvature between about .5 inches and about .9 inches since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Claims 22 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of jaws comprising a resilient material is new matter. The specification only describes clips made of resilient material but does not disclose that the jaws may be made of resilient material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (U.S. 5,921,996). Sherman discloses a clip applying apparatus including a handle assembly (26), a body portion defining a longitudinal axis (35), and a plurality of jaw mechanisms including first and second jaws having predefined radius of curvature, wherein the radius of curvature of the first and second jaws of each of the plurality of jaw mechanisms is different from the radius of curvature of each of the first and second jaws of each of the other of the plurality of jaw mechanisms (see last 3 lines of abstract, col. lines 36-39, col. 4 lines 14-24, and Fig. 2a-2f).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art

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are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

New Claims 21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarvik (U.S. 4,412,539). Jarvik discloses a clip applying apparatus comprising a handle assembly (58,98), a body portion (68) defining a longitudinal axis and extending distally from the handle assembly, a jaw mechanism including first and second jaws (44,46) configured to receive a clip therebetween, the first jaw being movable in relation to the second jaw between open and closed position, each jaw having a distal end, a proximal end extending out of the body portion and a lateral edge wherein from the proximal end to the distal end, the lateral edge moves in a direction spatially oriented from a lower elevation at the proximal end to a higher elevation at the distal end. In particular, Jarvik discloses curved jaws as seen in fig. 18. For the lateral edge of the jaws to move in a direction spatially oriented from a lower elevation at the proximal end to a higher elevation at the distal end depends entirely on the orientation of the device. The device can be held with the jaws curving in any direction. It is routine during surgical procedures to change the orientation of a hand-held surgical device in order to access different areas of tissue. Jarvik does not expressly disclose a radius of curvature between about 0.5 inch and about 0.9 inch for the curved jaws.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a radius of curvature of between 0.5 inch and 0.9 inch for the curved jaws of Jarvik because Applicant has not disclosed that this range of values provides any advantage, is used for a particular purpose, or solves a stated problem. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233). Therefore, it would have been prima facie obvious to modify Jarvik to obtain the invention as specified in claim 25 because such a modification would have been

considered a mere design consideration which fails to patentably distinguish over the prior art of Jarvik.

Regarding claim 23, the jaw mechanism can separate tissue from surrounding tissue and manipulate tissue at a surgical site. For example, a user can insert the jaws between two pieces of tissue, which would separate one tissue from the other. Once inserted, if the user moves the apparatus around, it will push on and move tissue as it is moved.

Regarding claim 24, see fig. 7, "138".

Regarding claim 25, Jarvik fails to disclose that the lateral edge has an overall radius of curvature with multiple and different radii. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide an overall radius of curvature with multiple and different radii for the curved jaws of Jarvik because Applicant has not disclosed that a changing radii provides any advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Jarvik and applicant's invention to perform equally well with either an overall radius of curvature with a constant radii or an overall radius of curvature with multiple and different radii because both provide curved jaws which increase visibility and can be used to manipulate tissue. Therefore, it would have been prima facie obvious to modify Jarvik to obtain the invention as specified in claim 25 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Jarvik.

New Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pistl et al. in view of Jarvik and Sherman (U.S. 5,921,996). Pistl et al. discloses a clip applying apparatus including a handle assembly (12), a body portion (7) defining a longitudinal axis and a clip carrying channel having a plurality of clips and a feed bar (2) configured to feed a clip from the plurality of clips to a jaw mechanism (col. 2 ll. 55-57). Pistl et al. fails to disclose that jaws are

curved and that a plurality of jaw mechanisms can be included in a kit with each set of jaws having a different radius of curvature.

However, Jarvik discloses that it is old and well known in the art to include jaws on a clip applying assembly that are curved in order to improve visibility at a surgical site (col. 9 ll. 33-38). Depending on the orientation of the device during use, the jaws curve upwardly. Sherman discloses that it is old and well known in the art that different shapes and sizes of clamps are needed for various procedures (last 3 lines of abstract; fig. 2a-2h). The invention of Sherman can advantageously be used for several different procedures since several different end effectors are provided that are compatible with the body and handle of the device. Clips also are used in a variety of surgical procedures and come in a variety of sizes and it would be useful to provide different jaw mechanisms that can fit the different clips. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Pistl et al. to curve the jaws as made obvious by Jarvik in order to gain the advantage of increased visibility and to further modify the device by providing a plurality of jaw mechanisms with different shapes and sizes (and therefore a different radius of curvature) as taught by Sherman in order to increase the amount of procedures in which the device can be used.

Claims 1, 2, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (U.S. 5,797,959). Castro et al. discloses an apparatus with a handle assembly (16), a body portion (22) defining a longitudinal axis and extending distally from the handle assembly and a jaw mechanism including first and second jaws (36, 38) configured to receive a clip there between. The first jaw is movable in relation to the second jaw between open and closed positions and each jaw is curved upwardly toward its distal end along the longitudinal axis of the body. Although shown pointing down in Fig. 1, the jaw assembly can be rotated by turning knob (40) so that the jaws point upwardly. Castro et al. does not disclose a radius of curvature

between about 0.5 inches and 0.9 inches. However, the criticality of such dimension is not disclosed in the specification of the instant application and therefore it is not a patentably distinct feature from the invention disclosed by Castro et al. Furthermore, the specification does not disclose any particular advantage gained or problem solved by using the particular dimensions. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to have modified Castro et al. such that the radius of curvature falls between 0.5 and 0.9 inches or is 0.7 inches because such a modification would have been considered a mere design consideration since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233) and therefore fails to patentably distinguish over Castro et al.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pistl (U.S. 5,626,586) in view of Klieman et al. (U.S. 4,325,376). Pistl discloses a clip applying apparatus including a handle assembly (11), a body portion (7), and a jaw mechanism including first and second jaws (6) configured to receive a clip there between, the first jaw being movable in relation to the second jaw between open and closed positions.

Regarding claim 3, the handle includes an actuation member (12) and the apparatus further includes a closure member (5) movably positioned within the body portion, the closure member being operably connected to the actuation member through an actuation stroke (col. 2 lines 33-36 and col. 3 lines 29-38).

Regarding claim 4, the jaw mechanism includes a body and first and second spaced shank members extending distally from the body, the first and second jaws extending from a distal end of the first and second shank members, respectively. First and second spaced shank members can be seen in Fig. 7. They are being considered the portion of the jaw mechanism

proximal to the portion of each of the jaw members that has the flattened engaging surface as seen in Fig. 7.

Regarding claim 5, the first and second shank members include a cam surface, the closure member being movable into engagement with the cam surface of the first and second shank members to move the first and second jaws from the open to closed position (see col. 4 lines 17-23).

Regarding claim 6, the jaw mechanism is one piece as seen in Fig. 7.

Regarding claim 7, the apparatus has a rotatable knob (13) that rotates the body portion and jaw mechanism in relation to the handle assembly (col. 2 lines 35-38).

Regarding claim 8, the actuation member includes a pivotable trigger (Fig. 1).

Pistl et al. discloses what appear to be curved jaw members in Fig. 2, but Pistl et al. does not expressly disclosed curved jaws in the text.

However, Klieman et al. discloses that it is old and well known to provide a jaw mechanism that has upwardly curved jaw members. Klieman et al. further discloses that the curved jaw members provide increased visibility during usage (col. 6 lines 59-63). Klieman et al. does not disclose a radius of curvature between about 0.5 inches and 0.9 inches. However, the criticality of such dimension is not disclosed in the specification of the instant application and therefore, it is not a patentably distinct feature from the invention disclosed by Klieman et al.. Furthermore, the specification does not disclose any particular advantage gained or problem solved by using the particular dimensions. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to have modified Klieman et al. such that the radius of curvature falls between 0.5 and 0.9 inches or is 0.7 inches because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Klieman et al. It would have been obvious to one of ordinary skill in

the art at the time of the invention to modify the device of Pistl et al. to include curved jaw members as made obvious by Klieman et al. in order to increase visibility for the surgeon during usage.

Regarding claims 9-11, Pistl discloses the invention substantially as stated above including clips which are supported between the first and second jaws, but fails to disclose that the clips have a pair of legs and a backspan or that the clips have the same radius of curvature as the jaw members.

However, Klieman et al. discloses that it is old and well known in the art to use clips that have a pair of legs and a backspan (Fig. 12, "37"). The clips disclosed by Klieman et al. are held between the jaws and are therefore sized to match the dimensions of the jaws. Klieman et al. further discloses that the clips are deformable (col. 3 line 66-col. 4 line 5). Using the deformable clips made obvious by Klieman et al. in the modified device of Pistl that has curved jaws would result in clips that are deformed into a shape with a radius of curvature matching the radius of curvature of the jaws. Deformable clips can be easily actuated by applying pressure to them and essentially clamping the arms together through the use of an open and closing jaw mechanism. Therefore, it would have been obvious to one of ordinary skill in the art to include deformable clips that have dimensions similar to the jaws as made obvious by Klieman et al. in the device disclosed by Pistl in order to gain the advantage of having an easy method of actuating the clips.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
9/15/2006


GLENN K. DAWSON
PRIMARY EXAMINER

